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10/510,497	10/07/2004	Shunji Hayashi	Q84102	1554

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
07/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/510,497	HAYASHI ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE 5/14/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 9-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 9-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2010 has been entered.

Claims 6 and 9-10 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 6 as presently amended recites, broadly, the incubation of a lactic acid bacteria starter in culture medium. Applicants refer to Example 3 to support the amendment in claim 6. However, Example 3 relates to only *L. gasseri* and *Lactococcus lactis* not to any lactic acid bacteria as presently claimed.

3. The amendment to claim 6 also includes "adding additional yeast extract to the raw milk". However, while in Example 3, additional yeast extract is added to the milk (for cheese making), the broad claim of "adding additional yeast extract to the raw milk" is not supported by the specification as originally filed. The specification as originally filed supports the addition of yeast extract but not the number of times it can be added.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 6 is indefinite for "incubating a lactic acid bacteria starter comprising a lactic acid bacteria with culture medium containing milk component where in yeast extract is added". It is not clear what the "milk component" is. It is not clear whether milk or any milk component such as lactose, whey proteins etc. is meant to be included in the culture medium.

7. Claim 6 is indefinite for "a lactic acid bacteria starter comprising a lactic acid bacteria". Since a lactic acid bacteria starter contains lactic acid bacteria, it is not clear what is meant by lactic acid bacteria comprising lactic acid bacteria.

8. Claim 10 is indefinite for "a mutant thereof". It is not clear whether the mutant has the same properties as the parent species regarding the disinfecting ability against *H. pylori*.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner et al. (1998, Development of a probiotic cheddar cheese containing human –derived Lactobacillus paracasei strains; hereinafter R1) in view of Anderson et al. (US 3,852, 158; hereinafter R2) , Germond et al. (WO 0188150, hereinafter R3) and Kimura et al. (EP 1 112 692 A1, hereinafter R4).

3. R1 reports the results of a research on the preparation of cheddar cheese containing live cultures of probiotic *Lactobacilli*. R1 confirms that L. paracasei strains grew and sustained high viability in cheese during ripening. (Abstract).

4. R1 discloses the process of producing the cheese where an inoculum of starter cultures is added to the pasteurized milk. In addition to the starter culture, a probiotic culture such as *L. paracasei* is also added. Cheddar cheese is then produced according to the standard process known in the art. Preparation of the curd, cutting and cooking the curds are all standard processes as taught by R1. The curds are pressed and kept as pressed overnight. The cheese in then removed from mold, vacuum packed and ripened at 8C for approximately 8.5 months. (page 2193, Col. 1, Cheddar cheese manufacture).

5. Given that the cheese was kept under press at ambient temperature overnight, it is clear that the bacteria, in the cheese, were exposed to temperatures and duration as presently claimed. Therefore the incubation overnight, at ambient temperature, was without cooling the curd as presently claimed.

6. R1 discloses that cheese made with *L. paracasei* contained high levels of these probiotic strains after 8 months of ripening with final counts of 10^7-10^8 CFU/g cheese. (page 2195, Col. 1, last two lines to Col. 2, first two lines).

7. R1 concludes that the probiotic *L. paracasei* strains incorporated into cheddar cheese are found to grow and proliferate to high cell numbers in cheese over 8 months even when they are added at a relatively small inoculum. R1 further discloses that the results of the present study indicate that Cheddar cheese offers potential as an effective vehicle for delivery of these strains to the consumer. (page 2198, Col. 1, Conclusion)

8. While R1 discloses the viability of certain probiotics in cheese as a delivery matrix, R1 is silent regarding the addition of yeast extract to the starter culture prior to activation of the culture. R1 is also silent regarding the incorporation of *Lactobacillus gasseri* into the cheese.

9. R2 discloses adding yeast extract to the starter cultures normally used in the manufacture of cheese. (Col. 2, lines, 3-7, 17-18, 36-47). Therefore, step (1) in claim 6 was known in the art at the time the invention was made.

10. Given that the utilization of yeast extract in cheese making is disclosed by R2, the addition of yeast extract to the starter medium culture or the milk (for cheese making) at any stage prior to the formation of curd would be obvious to those of skill in

the art. It is also noted that the addition of yeast extract before the formation of curd will assure a uniform distribution of the yeast extract in the whole body of cheese milk therefore, addition of yeast extract to the cheese milk prior to the formation of curd would have been logically obvious.

11. R2 is silent regarding the incorporation of *Lactobacillus gasseri* in cheese.

12. R3 discloses the incorporation of *L. gasseri* in dairy products including cheese. (page 3, lines 28-30; page 6, lines 2-4; claims 8-11)

13. R3 discloses the food compositions containing the probiotic organisms including *L. gasseri*. Therefore, employing cheese as a delivery vehicle for *L. gasseri* would have been obvious to an artisan.

14. R4 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [0001].

15. R4 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of $10^{\circ}C$ and viable count of more than 10^{7} cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be intrinsically high. Consequently the limitation of claim 6 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

16. R1 discloses the incorporation of probiotics in cheese where they can have a high rate of viability and recommends using cheese as a suitable vehicle to deliver such probiotics to consumers. R2 teaches of the addition of yeast extract or yeast autolysate for the activation and propagation of normal cheese starter cultures. R3 teaches of using cheese as a delivery system for *L. gasseri*. R4 clearly discloses the anti *Helicobacter pylori* properties of *Lactobacillus gasseri* strain OLL 2716 and how dairy foods may be used containing this probiotic. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to follow the teachings of R1 to make a cheese containing a probiotic and add yeast extract to the starter culture or the raw milk as taught by R2 and choose cheese as a delivery system for *L. gasseri* as taught by R3. The L. gasseri strain (OLL 2716) which has anti H. pylori properties would have been chosen logically for that benefit, as taught by R4. One would do so to produce a cheese which can contain a high number of a probiotic organisms such as *Lactobacillus gasseri* and use it as an efficient matrix for delivery of probiotics to the consumers. Absent any evidence to the contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to incorporate a probiotic organism such as *Lactobacillus gasseri* in cheese as presently claimed.

Response to Arguments

Applicants' arguments have been reviewed. These arguments are not persuasive for the following reasons.

1. Applicants argue that in the presently claimed process, yeast extract is added twice i.e. once to the starter culture and once to the milk before the formation of curd.

a. In the new ground(s) of rejection set forth in this Office action, R2 discloses the utilization of yeast extract in the activation and propagation of starter cultures normally used in cheese making. Once this is disclosed in the art, addition at any stage in the cheese making before the formation of curd would be obvious.

b. The addition of yeast extract at two stages is only supported by Example 3. The specification, in general, calls for the addition of yeast extract and is silent for the use of yeast extract at two stages.

2. Applicants argue that R1 is concerned with L. paracasei and it is not reasonable to assume that L. paracasei (disclosed by R1) and L. gasseri strains would be interchangeable to produce predictable results with reasonable expectation of success.

a. It should be realized that R2 discloses the utilization of yeast extract in the activation of the propagation of starter cultures. R3 clearly teaches of incorporating L. gasseri in cheese as a suitable delivery system. Therefore, when the yeast extract is included in the cheese together with L. gasseri, the result of high viability of L. gasseri would be reasonably expected.

3. Applicants argue that based on the findings of a research article, provided by the Applicants, it can be easily understood that L. gasseri would show a lower viability than L. paracasei in cheese over the time.

a. Since the incorporation of L. gasseri into cheese together with yeast extract were disclosed by R2 and R3, utilization of this organism and yeast extract in the method of

R1 for making cheese would result in a cheese containing L. gasseri with high survival rate for the duration of time as presently claimed.

4. Applicants argue that adding yeast extract as growth activator by R2 does not take place before formation of the curd.

a. The previous reference designated as R2 has been omitted from this Office action. In light of the new ground(s) of rejection, this argument is moot.

5. Applicants argue that the presently amended claim 6 requires the addition of yeast extract twice during the course of the process.

a. As mentioned above, the addition of yeast extract at two stages is only supported by Example 3. The specification is generally silent regarding the yeast extract addition twice. Further, since the addition of yeast extract to the starter culture used in cheese making is disclosed by R2, additions at any stage before the curd formation would be obvious to an artisan.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,578,988 to Hori et al. This reference discloses the addition of starter culture to raw milk (Example 2).

JP 2001-000143-A: Incorporation of L. gasseri OLL 2716 into food products for anti H. pylori effect.

JP H08-116872-A: Promoting the proliferation of Lactobacilli.

JP H07-236484-A : Incorporating L. gasseri into cheese.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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